

Remarks/Arguments

Applicants have received and carefully reviewed the Office Action of the Examiner mailed October 17, 2007. Currently, claims 1-36 remain pending. Claims 1-36 have been rejected. Favorable consideration of the following remarks is respectfully requested.

Claim Rejections – 35 USC § 102

Claims 1-36 stand rejected under 35 USC § 102 as anticipated by Vale et al. (Published U.S. Patent Application No. 2002/0058963), hereinafter *Vale*. After careful review, Applicant must respectfully traverse this rejection. The Examiner, in his Response to Arguments, has chosen to rely entirely upon a reproduction of Fig. 13 and has supplied labels purporting to identify the arrowhead bulge of the centering catheter tube 20 of *Vale* as a “proximal section”. While distal and proximal are relative terms, *Vale* explicitly identifies the arrowhead 50 portion of centering catheter tube 20 as the *distal* end of centering catheter tube 20 at paragraph [0085]: “the distal end of the centering catheter tube 20 is in the shape of an arrowhead 50” and repeats as: “The largest outer diameter d_1 of the distal end 50 of the centering catheter 11”, which largest outer diameter of the *distal* end of the centering catheter the Examiner incorrectly identified as a proximal section in contradiction to the specification and drawings provided by the Applicant. *Vale* consistently refers to the arrowhead 50 of the centering catheter as the distal end in eight additional places. It should also be noted that *Vale* specifies, in paragraph [0085], that the diameter of the centering catheter, exclusive of the distal arrowhead, is *less than* the interior dimension of the retrieval catheter thus providing more lumen space therebetween and precluding the expanding fit contemplated in the pending application. Indeed, as illustrated in the cited Fig. 13, the maximum diameter of the distal arrowhead of *Vale* is significantly smaller than the interior diameter of the retrieval catheter.

Figs. 1 and 2 of the pending application identify the “proximal section” of the dilator tip explicitly by reference numeral 30 (See page 8, line 9 and page 9, line 15.) Accordingly, it is believed that the claims previously presented were in allowable form,

however, in order to advance prosecution, the claims have been amended, as appropriate, to clarify that the proximal end 40 of dilator tip 28 lies within the distal segment of the elongated tube member. No new matter has been introduced. Attention is drawn to the fact that the proximal end 22 of the centering catheter as identified by *Vale* extends proximally from the proximal end of the retrieval catheter in paragraph [0012] and [0073] as well as in Fig. 1, the only places where it appears, and so cannot lie within the distal end of the retrieval catheter.

In paragraph 2 of the Office Action, claims 1, 4-11, 22, and 25-36 were rejected under 35 U.S.C. 102(b) as being anticipated by *Vale et al.* (U.S. Publication No. 2002/0058963). After careful review, Applicant must respectfully traverse this rejection.

Turning to claim 1, which recites:

1. (Currently Amended) A medical device, comprising:
 - an elongated tubular member having a proximal segment, a distal segment, and an inner lumen disposed at least partially therethrough; and
 - a dilator tip having a proximal end insertable at least in part within the distal segment;
- wherein the proximal section of the dilator tip has an outer diameter and the distal segment of the elongated tubular member has an inner diameter smaller than the outer diameter of the proximal section of the dilator tip;
- wherein a proximal end of the dilator tip is positioned at least in part within the distal segment of the elongated tubular member such that the distal segment expands around at least a portion of the proximal section of the dilator tip.

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). “The identical invention must be shown in as complete detail as is contained in the ... claim.” *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). (See MPEP § 2131).

Nowhere does *Vale et al.* appear to teach or suggest, “wherein the proximal section of the dilator tip has an outer diameter and the distal segment of the elongated tubular member has an inner diameter smaller than the outer diameter of the proximal section of the dilator tip” or “wherein the proximal end of the dilator tip is positioned at least in part

within the distal segment of the elongated tubular member such that the distal segment expands around at least a portion of the proximal end of the dilator tip", as recited in claim 1.

Instead, Vale et al. appears to teach a retrieval catheter 70 having a tapered distal tip 71. A centering catheter tube 20 is inserted within the retrieval catheter 70. However, the proximal section of the centering catheter tube 20 appears to have an outer diameter less than the inner diameter of the retrieval catheter. Also, nowhere does the retrieval catheter 70 appear to expand around at least a portion of the proximal section of the centering catheter tube 20. To further illustrate this, Vale et al. recites:

[0085] Referring now to FIGS. 10 to 12 in another embodiment of the invention, the distal end of the centering catheter tube 20 is in the shape of an arrowhead 50. The largest outer diameter d_1 of the distal end 50 of the centering catheter 11 is equal to the outer diameter d_2 of the retrieval catheter tip 19 at the open mouth 40. This ensures that there is a smooth, step free crossing profile between the centering catheter distal end 50 and the retrieval catheter tip 19 in the advancement mode of FIG. 11. Also the distal end 50 of the centering catheter tube 20 sealingly engages the retrieval catheter tip 19 in the advancement mode. This enables a centering catheter tube 20 with a diameter d_3 which is smaller than d_1 to be used, thus providing more lumen space between the centering catheter tube 20 and the retrieval catheter 10 to facilitate flushing and/or aspiration.

[0090] Referring now to FIG. 18 in another embodiment of the invention the diameter of the retrieval catheter 10 varies along its longitudinal length. In this case the diameter d_1 of the tip 19 of the retrieval catheter 10 is greater than the diameter d_r of the remaining length of the retrieval catheter tube 15. The diameter d_1 of the tip 19 of the retrieval catheter 10 is equal to or greater than the diameter d_g of the guide catheter 42. This allows a retrieval catheter tube 15 of smaller diameter to be used, thus providing more lumen space between the retrieval catheter tube 15 and the guide catheter 42. This extra lumen space enables the injection of contrast media and the like through the guide catheter 42.

[0091] Referring to FIG. 19 there is illustrated another retrieval device 41 according to the invention, which is similar to the retrieval device 1 and like parts are assigned the same reference numerals. In this case the retrieval catheter 41 comprises a guide catheter 60 and a centering catheter 11, and a separate retrieval catheter is not required. The guide catheter 60 is of sufficiently small diameter to allow it to be advanced to the site of the stenosis 30, and the distal end 50 of the centering catheter 11 in the shape of an arrowhead is sized to match the outer diameter of the guide catheter 60. The largest outer diameter d_2 of the distal end 50 is equal to the outer

diameter d₄ of the guide catheter 60. This ensures a smooth, step-free transition between the centering catheter 11 and the guide catheter 60.

[0093] The centering catheter 11 also provides support to the retrieval catheter assembly, greatly enhancing the integrity and kink resistance of the system, so that an ultra low profile, thin wall retrieval catheter 10 can be used without compromising the integrity of the system. This provides a very large lumen within the tip 19 of the retrieval catheter 10 to facilitate the retrieval of large filters with large volumes of captured embolic material. In one embodiment of the invention the centering catheter has an inner diameter of 0.76 mm and an outer diameter of 1.63 mm, and the retrieval catheter has an inner diameter of 1.78 mm and an outer diameter of 2.08 mm. These dimensions are given as examples only and are by no means essential to the invention. It will be appreciated that other diameters may also be used to obtain a retrieval system with structural integrity and a large retrieval lumen.

Therefore, as can be clearly seen, Vale et al. does not teach each and every element of claim 1 in as complete of detail. Thus, claim 1 is believed to be not anticipated by Vale et al. and Applicant respectfully requests withdrawal of the rejection.

Additionally, for similar reasons, as well as others, claims 4-11, which depend from claim 1 and include significant additional limitations, are believed to be not anticipated by Vale et al. and Applicant respectfully requests withdrawal of the rejection.

Turning to claim 22, which recites:

22. (Previously Presented) A medical device, comprising:
an elongated tubular member having a proximal segment, a distal segment, and an inner lumen disposed at least partially therethrough, the distal segment having an inner diameter; and

a dilator tip insertable at least in part within the distal segment, the dilator tip having a proximal section having an outer diameter greater than the inner diameter of the distal segment of the elongated tubular member forming an interference fit therebetween, a distal section, and an inner lumen disposed therethrough;

wherein the interference fit between the dilator tip and the distal segment of the elongated tubular member causes the distal segment of the elongated tubular member to be radially expanded.

Nowhere does Vale et al. appear to teach or suggest, “a dilator tip insertable at least in part within the distal segment, the dilator tip having a proximal section having an outer diameter greater than the inner diameter of the distal segment of the elongated tubular member forming an interference fit therebetween, a distal section, and an inner lumen disposed therethrough” or “wherein the interference fit between the dilator tip and the

distal segment of the elongated tubular member causes the distal segment of the elongated tubular member to be radially expanded", as recited in claims 22. Therefore, for similar reasons discussed above, as well as others, claim 22 is believed to be not anticipated by Vale et al. and Applicant respectfully requests withdrawal of the rejection.

Additionally, for similar reasons, as well as others, claims 25-30, which depend from claim 22 and include significant additional limitations, are believed to be not anticipated by Vale et al. and Applicant respectfully requests withdrawal of the rejection.

Turning to claim 31, which recites:

31. (Previously Presented) A system for retrieving an intravascular device disposed within a body lumen, comprising:
- an embolic protection filter disposed about an elongated wire;
 - a retrieval device configured to radially expand and encompass the intravascular filter therein, said retrieval device comprising an elongated tubular member having a proximal segment, a distal segment, and an inner lumen adapted to slidably receive the elongated wire; and
 - a dilator tip having a proximal section insertable at least in part within the distal segment urging the distal segment of the elongated tubular member to radially expand, said dilator tip configured to engage a stop disposed about the elongated wire.

Nowhere does Vale et al. appear to teach or suggest, "a dilator tip having a proximal section insertable at least in part within the distal segment urging the distal segment of the elongated tubular member to radially expand, said dilator tip configured to engage a stop disposed about the elongated wire", as recited in claim 31. Therefore, for similar reasons discussed above, as well as others, claim 31 is believed to be not anticipated by Vale et al. and Applicant respectfully requests withdrawal of the rejection.

Turning to claim 32, which recites:

32. (Currently Amended) A system for retrieving an intravascular device disposed within a body lumen, comprising:
- an embolic protection filter disposed about an elongated wire;
 - a retrieval device configured to radially expand and encompass the intravascular filter therein, said retrieval device comprising an elongated tubular member having a proximal segment, a distal segment, and an inner lumen adapted to slidably receive the elongated wire; and
 - a dilator tip insertable at least in part within the distal segment, the dilator tip including a proximal section configured to tightly fit within the distal segment, a distal section configured to engage a stop disposed about the elongated wire, and an inner lumen disposed therethrough configured to slidably receive the elongated wire;

wherein the proximal section of the dilator tip has an outer diameter and the distal segment of the elongated tubular member has an inner diameter smaller than the outer diameter of the proximal section of the dilator tip;

wherein a proximal end of the dilator tip is positioned at least in part within the distal segment of the elongated tubular member such that the distal segment expands around the proximal section of the dilator tip.

Nowhere does Vale et al. appear to teach or suggest, “a dilator tip insertable at least in part within the distal segment, the dilator tip including a proximal section configured to tightly fit within the distal segment, a distal section configured to engage a stop disposed about the elongated wire, and an inner lumen disposed therethrough configured to slidably receive the elongated wire”, “wherein the proximal section of the dilator tip has an outer diameter and the distal segment of the elongated tubular member has an inner diameter smaller than the outer diameter of the proximal section of the dilator tip”, or “wherein the proximal end of the dilator tip is positioned at least in part within the distal segment of the elongated tubular member such that the distal segment expands around the proximal section of the dilator tip”, as recited in claim 32. Therefore, for similar reasons discussed above, as well as others, claim 32 is believed to be not anticipated by Vale et al. and Applicant respectfully requests withdrawal of the rejection.

Turning to claim 33, which recites:

33. (Currently Amended) A medical device, comprising:
an elongated tubular member having a proximal segment, a distal segment, and an inner lumen disposed at least partially therethrough, the distal segment formed of an elastic material such that the distal segment is radially expandable between an unexpanded state and a radially expanded state; and

a dilator tip including a proximal section, a proximal end of the dilator tip inserted at least in part within the distal segment, wherein the proximal section of the dilator tip urges the distal segment of the elongated tubular member into the radially expanded state.

Nowhere does Vale et al. appear to teach or suggest, “a dilator tip including a proximal section, a proximal end of the dilator tip inserted at least in part within the distal segment, wherein the proximal section of the dilator tip urges the distal segment of the elongated tubular member into the radially expanded state”, as recited in claim 33. Therefore, for similar reasons discussed above, as well as others, claim 33 is believed to be not

anticipated by Vale et al. and Applicant respectfully requests withdrawal of the rejection.

Additionally, for similar reasons, as well as others, claims 34-36, which depend from claim 33 and include significant additional limitations, are believed to be not anticipated by Vale et al. and Applicant respectfully requests withdrawal of the rejection.

Claim Rejections – 35 USC § 103

In paragraph 15 of the Office Action, claims 2 and 23 were rejected under 35 U.S.C. 103(a) as being unpatentable over Vale et al. (U.S. Publication No. 2002/0058963) in view of Nilsson (U.S. Patent No. 5,873,851). After careful review, Applicant must respectfully traverse this rejection.

For similar reasons given above, as well as others, claims 2 and 23, which depend from claims 1 and 22 and include significant additional limitations, are believed to be patentable over Vale et al. and Nilsson and Applicant respectfully requests withdrawal of the rejection.

In paragraph 16 of the Office Action, claims 3 and 24 were rejected under 35 U.S.C. 103(a) as being unpatentable over Vale et al. (U.S. Publication No. 2002/0058963) in view of Salahieh et al. (U.S. Publication No. 2004/0127936). After careful review, Applicant must respectfully traverse this rejection.

For similar reasons given above, as well as others, claims 3 and 24, which depend from claims 1 and 22 and include significant additional limitations, are believed to be patentable over Vale et al. and Salahieh et al. and Applicant respectfully requests withdrawal of the rejection.

In paragraph 17 of the Office Action, claims 12 and 14-21 were rejected under 35 U.S.C. 103(a) as being unpatentable over Vale et al. (U.S. Publication No. 2002/0058963) in view of Salahieh et al. (U.S. Publication No. 2004/0058963). After careful review, Applicant must respectfully traverse this rejection.

Turning to claim 12, which recites:

12. (Previously Presented) A medical device, comprising:
an elongated tubular member having a proximal segment, a distal segment, and an inner lumen disposed at least partially therethrough, the distal segment including at least a portion including a braid, the distal segment configured to radially expand between an unexpanded state and a radially expanded state; and

a dilator tip having a proximal section inserted at least in part within the portion of the distal segment including the braid, wherein the proximal section of the dilator tip urges the distal segment of the elongated tubular member into the radially expanded state.

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). (See MPEP § 2143.01). As discussed previously, nowhere does Vale et al. appear to teach or suggest, “a dilator tip having a proximal section inserted at least in part within the portion of the distal segment including the braid, wherein the proximal section of the dilator tip urges the distal segment of the elongated tubular member into the radially expanded state”, as recited in claim 12. Furthermore, nowhere does Salahieh et al. appear to remedy the shortcomings of Vale et al. Therefore, for similar reasons discussed above, as well as others, claim 12 is believed to be patentable over Vale et al. in view of Salahieh et al. and Applicant respectfully requests withdrawal of the rejection.

Additionally, for similar reasons given above, as well as others, claims 14-21, which depend from claim 12 and include significant additional limitations, are believed to be patentable over Vale et al. and Salahieh et al. and Applicant respectfully requests withdrawal of the rejection.

In paragraph 25 of the Office Action, claim 13 was rejected under 35 U.S.C. 103(a) as being unpatentable over Vale et al. (U.S. Publication No. 2002/0058963) in view of Salahieh et al. (U.S. Publication No. 2004/0127936) and further in view of Nilsson (U.S. Patent No. 5,873,851). After careful review, Applicant must respectfully traverse this rejection.

For similar reasons given above, as well as others, claim 13, which depends from claims 12 and includes significant additional limitations, is believed to be patentable over Vale et al. and Salahieh et al. and further in view of Nilsson and Applicant respectfully requests withdrawal of the rejection.

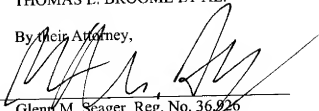
In view of the foregoing, all pending claims, namely claims 1-36, are believed to be in a condition for allowance. Reexamination and reconsideration are respectfully requested. Issuance of a Notice of Allowance in due course is anticipated. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

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By their Attorney,

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